

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 February 2002 (21.02.2002)

PCT

(10) International Publication Number
WO 02/14537 A3

(51) International Patent Classification⁷: **A61K 31/195,**
G01N 33/00, A61K 38/22

CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM,
HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK,
LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX,
MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL,
TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(22) International Filing Date: 14 August 2001 (14.08.2001)

(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD,
TG).

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/224,991 14 August 2000 (14.08.2000) US

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(71) Applicant and
(72) Inventor: FALLON, Joan, M. [US/US]; 1234 Central Avenue, Suite 1B, Yonkers, NY 10704 (US).

(74) Agents: DEROSA, Frank, V. et al.; F. Chau & Associates, LLP, 1900 Hempstead Turnpike, Suite 501, East Meadow, NY 11554 (US).

(88) Date of publication of the international search report:
10 May 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



WO 02/14537 A3

(54) Title: METHODS FOR DIAGNOSING AND TREATING DYSAUTONOMIA AND OTHER DYSAUTONOMIC CONDITIONS

(57) Abstract: Methods for aiding in the diagnosis of dysautonomic disorders and dysautonomic conditions and methods for treating individuals diagnosed as having a dysautonomic disorder or a dysautonomic condition. In one aspect, a diagnosis method comprising analyzing a stool sample of an individual for the presence of a biological marker wherein the quantity of the biological marker is an indication of whether the individual has, or can develop, a dysautonomic disorder or dysautonomic condition, as well as a therapeutic method for treating a dysautonomic disorder or dysautonomic condition by administration of, e.g., secretin, neuropeptides, peptides and/or digestive enzymes.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/25343

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K31/195 G01N33/00 A61K38/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, CHEM ABS Data, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>AXELROD, FELICIA: "Grant Receipt awards March - May 2000. Secretin treatment for gastrointestinal dysmobility in patients with familial dysautonomia" INTERNET: NEY YORK UNIVERSITY OF MEDICINE, 'Online! XP002191208 Retrieved from the Internet: <URL:mcrccr4.med.nyu.edu/ogars/awards/awards_2000/page2.html> 'retrieved on 2002-02-25! the whole document ---</p>	1
A	<p>US 5 958 875 A (MANTHORPE MARSTON ET AL) 28 September 1999 (1999-09-28) column 10, line 11 - line 23; claims 1-14 --- -/-</p>	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

25 February 2002

Date of mailing of the international search report

11/03/2002

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Stienon, P

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/25343

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 22499 A (BRAUN PETER ERICH ; MCKERRACHER LISA JOAN (CA); DAVID SAMUEL (CA);) 28 May 1998 (1998-05-28) claims 1-47 ----	
A	US 5 648 335 A (LEWIS MICHAEL E ET AL) 15 July 1997 (1997-07-15) column 8, line 38 - line 51; claims 1-3 ----	
A	WO 95 22344 A (BRAUN PETER ERICH ; MCKERRACHER LISA JOAN (CA); UNIV MCGILL (CA); D) 24 August 1995 (1995-08-24) claims 1-13 ----	
A	EP 0 564 739 A (YSSUM RESEARCH DEVELOPMENT CO OF THE HEBREW UNIVERSITY OF JERUSALEM) 13 October 1993 (1993-10-13) page 14, line 56 -page 15, line 6 ----	
A	US 6 020 314 A (MCMICHAEL JOHN) 1 February 2000 (2000-02-01) abstract ----	
A	WO 99 64059 A (REPLIGEN CORP) 16 December 1999 (1999-12-16) abstract -----	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 1-57 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the secretin compound/composition.

Continuation of Box I.1

Rule 39.1(iv) PCT – Method for treatment of the human or animal body by therapy

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/25343

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 5958875	A	28-09-1999	AU WO	2426497 A 9736607 A1	22-10-1997 09-10-1997

WO 9822499	A	28-05-1998	CA AU WO	2190418 A1 5044298 A 9822499 A2	15-05-1998 10-06-1998 28-05-1998

US 5648335	A	15-07-1997	US US AT AU CA DE DE DK EP ES GR HU JP NO NZ NZ PT WO US RU	5569648 A 5420112 A 187889 T 683215 B2 4526293 A 2136969 A1 69327402 D1 69327402 T2 659083 T3 0659083 A1 2140463 T3 3032844 T3 70450 A2 7507799 T 944780 A 253867 A 280523 A 659083 T 9325219 A1 5633228 A 2120803 C1	29-10-1996 30-05-1995 15-01-2000 06-11-1997 04-01-1994 23-12-1993 27-01-2000 04-05-2000 13-06-2000 28-06-1995 01-03-2000 31-07-2000 30-10-1995 31-08-1995 09-12-1994 27-08-1996 27-07-1997 31-05-2000 23-12-1993 27-05-1997 27-10-1998

WO 9522344	A	24-08-1995	AU CA WO	1703595 A 2183630 A1 9522344 A1	04-09-1995 24-08-1995 24-08-1995

EP 0564739	A	13-10-1993	AT DE DE EP JP US US	189228 T 69230610 D1 69230610 T2 0564739 A2 6263797 A 5723575 A 6117974 A	15-02-2000 02-03-2000 28-12-2000 13-10-1993 20-09-1994 03-03-1998 12-09-2000

US 6020314	A	01-02-2000	AU EP WO	4985499 A 1105147 A1 0009142 A1	06-03-2000 13-06-2001 24-02-2000

WO 9964059	A	16-12-1999	US AU EP WO US	6197746 B1 4432299 A 1085901 A2 9964059 A2 2001049353 A1	06-03-2001 30-12-1999 28-03-2001 16-12-1999 06-12-2001
